

#### PEREGRINO FERREIRA S.N. 09/759,281

### REMARKS

This application has been amended in a manner that is believed to place it condition for allowance at the time of the next Official Action.

Claims 1, 2 and 6 were pending in the present application. Claims 1 and 2 are directed to a recombinant protein. Claim 6 is directed to a reagent kit.

In the outstanding Official Action, claims 1, 2 and 6 were rejected under 35 USC §112, second paragraph, as allegedly being indefinite. This rejection is respectfully traversed.

Claims 2 and 6 have been amended to more particularly point out and distinctly claim the subject matter which Applicants regard as the invention. Claim 2 has been amended to recite a recombinant protein consisting of Seq. ID No. 1. Claim 6 has been amended to recite a reagent kit comprising a protein according to claim 1. Thus, it is believed that claims 1, 2 and 6 have been amended in a manner so that they are definite to one of ordinary skill in the art.

In the outstanding Official Action, claims 1, 2 and 6 were rejected as allegedly being anticipated by or, in the alternative, under 35 USC §103(a) as obvious in view of BIRKETT et al. or KONG et al. However, Applicants respectfully submit that these cited publications fail to qualify as prior art.

The outstanding Official Action stated that the present application is a continuation-in-part of U.S. Application



09/331,362 filed on July 13, 1999. The Official Action contends that Seq. ID No. 1 was not disclosed in U.S. application 09/331,362 and that all claims reciting Seq. ID No. 1 in the present application are only entitled to the filing date of the present application of January 16, 2001. However, Applicants respectfully traverse this assertion.

While the amino acid sequence of Seq. ID No. 1 is recited in the present application, Applicants respectfully submit that Seq. ID No. 1 only serves to further characterize the protein of the claimed invention. Applicants respectfully submit that the parent application and priority documents clearly set forth that Applicants had possession of the claimed protein prior to submission of the sequence listing.

Thus, Applicants believe that the present application is entitled to claim priority to the PCT/BR97/00081 application filed on December 19, 1997 and the Brazilian application No. Pl 9606273-8 filed on December 18, 1996. As a result, Applicants respectfully submit that the cited publications of BIRKETT et al. (published in 1997) and KONG et al. (published in 1997) fail to qualify as prior art.

While Applicants believe the cited publications fail to qualify as prior art, in the interest of being fully responsive to the outstanding Official Action, Applicants will address the cited publications on their merits as follows.



Claims 1, 2 and 6 were rejected under 35 USC §102(b) as allegedly being anticipated by or, in the alternative, under 35 USC §103(a) as obvious in view of BIRKETT et al. This rejection is respectfully traversed.

Applicants respectfully submit that BIRKETT et al. fail to disclose or suggest the claimed invention. Applicants believe that the BIRKETT et al. publication fails to suggest the claimed protein of the present application. The Examiner's attention is respectfully directed to page 63 of BIRKETT et al., wherein it is stated that the major EAIV core share proteins of other members of the Lentivirus family; most notably a 55% amino acid similarity (30% identity) with major core antigen of HIV-1p24. Indeed, serum from EIAV infected horses has been shown to precipitate the major core antigens of HIV-1 and FIV". However, even minor differences in sequences can result in significant structural differences. These structural differences may result in an entirely different three-dimensional structure and exhibit antiqenicity. Thus, Applicants different functions and respectfully submit that as BIRKETT et al. fail to disclose the full length amino acid sequence, one of ordinary skill in the art would not obtain the specific antigenicity of the viral core protein. Thus, BIRKETT et al. fails to disclose or suggest the claimed invention.

Applicants also note that there is a difference in the recombinant core protein and the actual viral core protein.



Applicants respectfully submit that the sequence differs not only with regard to the amino terminal end but also to particular positions further down the sequence. The Examiner's attention is respectfully directed to page 63 of BIRKETT et al. which states "recombinant core protein differs from the actual viral core protein which is 230 amino acids long, by having two less amino acids, PRO and ILE, at the amino terminus, VAL instead of ILE as the second amino acid in the five amino acid extension at the carboxyl terminus between P26 and P11". However, in the amino acid sequence of the present invention, PRO is not followed by ILE and there is no ILE in the first thirty amino acid sequence. Moreover, Applicants note that Seq. ID No. 1 set forth in the claimed invention recites additional amino acids. Thus, it is respectfully submitted that BIRKETT et al. fail to disclose or suggest the claimed invention.

Claims 1, 2 and 6 were further rejected under 35 USC \$102(b) as allegedly being anticipated by or, in the alternative, under 35 USC \$103(a) as allegedly being obvious over KONG et al. This rejection is respectfully traversed.

Applicants respectfully submit that KONG et al. fail to disclose each and every recitation of the claimed invention. Applicants believe that KONG et al. fail to disclose or suggest he claimed protein. The Examiner's attention is respectfully directed to page 976 in KONG et al. KONG et al. disclose that the primers for PCR amplification of the gag and



P26 gene is prepared on the basis of the sequence of the EIAV Wyoming strain. In doing so KONG et al. cite to Kawakami et al. (Nucleotide Sequence Analysis of Equine Infectious Anemia Virus Provile DNA. Virology, Vol. 158, page 300-312, 1987) as teaching the method for preparing the genes based on the sequence of the EIAV Wyoming strain. As a result, Applicants assume that the amino acid sequence obtained by KONG et al. was exactly the same as deposited in genbank access No. M16575, K03334, M11337 or M14855.

The Examiner's attention is respectfully directed to annex 1 and annex 2 attached with this amendment. Annex 1 shows a blast illustration of the two sequences. Annex 2 shows the sequence utilized by Kawa Kami et al. When the two sequences are compared, it is very clear that the sequences are distinct. There is an additional assertion of fourteen amino acids between the Kawa Kawi et al. sequence and the sequence of the claimed invention. As one of ordinary skill in the art would appreciate in the protein field, an assertion of an additional fourteen amino acids is significant. Applicants submit that KONG et al. fail to disclose or suggest the claimed invention.

In view of the present amendment and the foregoing remarks, therefore, it is believed that this application is now in condition for allowance, with claims 1, 2 and 6, as presented. Allowance and passage to issue on that basis are accordingly respectfully requested.



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## PEREGRINO FERREIRA S.N. 09/759,281

# <u>VERSION WITH MARKINGS TO SHOW CHANGES MADE</u>

Claim 2 has been amended as follows:

--2. (amended) A recombinant protein [having the sequence] consisting of SEQ ID NO:1.--

Claim 6 has been amended as follows:

--6. (amended) A reagent kit [characterized in that it includes] comprising a protein according to claim 1.--